Marketing permission given by State Drug Authorities without Trial reports

2125. SHRIMATI RATAN KUMARI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that certain State Drug Authorities have given the manufacturing and marketing permission without trial reports and without studying the rational in respect to combination of drugs and ointments;

(b) what are the combination of drugs and ointments cleared by the State Drug Authorities of Andhra Pradesh, Bihar, Gujarat and Haryana during the last two years ending 31st December, 1988;

(c) whether Government have examined all these products;

(c) whether Government are satisfied about the efficacy, safety and rational of these products;

(e) the names of products which have been found non-effective, hazardous and unsafe; and

(f) what are the indications for which each of these products have been cleared and names of the countries where each of them is marketed?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (d) Licensing Authorities appointed by the State Governments for their respective States grant licences to manufacture drug/drug combination. There was, however, no uniformity in granting of licence for manufacture of combinations. In order to streamline licensing of combination, the Central Government have recently amended the provisions of the Drugs and Cosmetics Rules, 1945. This step has been taken to safeguard against licensing of irrational combination of drugs by the licensing authorities appointed by the State Governments and to ensure that necessary technical data is furnished before registering a combination.

Since the licence to manufacture drugs are granted by the licensing authorities appointed by the State Governments, the Central Government do not have the details of the combinations permitted for marketing in different States.

However, a sub-committee of experts appointed by Drugs Consultative Committee is seized with the examination of formulations including combinations moving in the market from the angle of safety, efficacy and rationality. This is a continuous process.

(e) and (f) Based on the recommendations of experts and Drugs Technical Advisory Board, Government have prohibited manufacture and sale of 27 categories of formulations licensed by the State Authorities (List annexed).

List of drugs formulations banned under Section 26A of the Drugs Cosmetics Act, 1940

1. Amidopyrine.
2. Fixed dose combinations of vitamine with antiinfiamatory agents and tranquillisers;
3. Fixed does combination of Atropine in Analgesics and Antiypyretics.
4. Fixed dose combination of Strychine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
6. Fixed dose combinations of Iron with Straychline, Aresanic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/Chloral hydrate with other drugs.
8. Phenacatin.

9. Fixed dose combinations of antihistaminics with anti-diarrhoeals

10. Fixed dose combinations of Penicillin with Sulphonamides.

11. Fixed dose combination of Vitamins with Analgesics.

12. Fixed dose combinations of Tetracycline with Vit. 'C'.

13. Fixed dose combination of Hydroxyquinoline group of Drugs except preparations which are used for the treatment of diarrhoea and dysentry and for external use only.

14. Fixed dose combinations of Corticosteroids with any other drug for internal use.

15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.

16. Fixed dose combination of Erget.

17. Fixed dose combinations of Vitamine with Anti T. B. drugs except combination of Isoniazide with Pyridoxine Hydrochloride (Vitamin. B. 6).

18. Pencillin skin/eye ointment.

19. Tetracycline liquid oral preparations-

20. Nialamide.

21. Practolol.

22. Mathapyrilene, its salts.

23. Mothaqualone.

24. Oxytetracycine Liquid Oral Preparations.

25. Democlocycline Liquid Oral Preparations.

26. Combination of Anabolic Steroids with other drugs.

27. Fixed dose combination of Oestrogen and Progestin (other than oral contraceptives) containing per tablet ostrogen content of more than 50mcg. (equivalent to Ethenyle Estradiol) and of progestine content of more than 3 mg. (equivalent to Norethisteren Acetate).

Marketing of Drugs containing Strychnine in the Country.

2126. DR. (SHRIMATI) SAROJINI MAHISHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that drugs containing Strychnine are allowed for marketing for human consumption in the country;

(b) if so, what is the rational of such combinations;

(c) whether it is a fact such combinations are banned or withdrawn in certain countries;

(d) if so, the names of those countries;

(e) what are the names of formulations being marketed in the country;

(f) what are the names of the manufacturers of such products; and

(g) what are the details of indication of each drug as well as contra-indications?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) No, Sir. Use of Strychnine in fixed dose combination is banned.

(b) to (g) Do not arise.

Import of Gentamycin

2127. SHRI BEKAL UTSAHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) wheher it is a fact that Gentamycin is allowed for import;

(b) if so, what was the total quantity imported in he country during the last two years;